

Notice of Allowability

Application No.

10/080,043

Examiner

Phyllis G. Spivack

Applicant(s)

HU ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment filed April 25, 2006 and the telephone interview of August 28, 2006.
2. ☒ The allowed claim(s) is/are 5,7,9 and 11.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 6-6-06; 8-28-06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other The figures are accepted.

8-28-06

EXAMINER'S AMENDMENT

The subject matter of the Abstract is deleted and -- - The P450 3A (CYP3A) inhibitor swertiamarin, when co-administered with a drug, improves the drug's bioavailability. -- is inserted therefor.

Authorization for the Examiner's Amendment as set forth below was given in a telephone interview with Dr. Fei-Fei Chao on June 6, 2006.

Claims 1 and 26 are canceled.

In claim 5, line 2, "a CYP3A inhibitor" is deleted and -- the CYP3A inhibitor swertiamarin -- is inserted therefor. The subject matter on line 5 is deleted after "acceptable salt". Lines 6 and 7 of claim 5 are deleted.

Authorization for the Examiner's Amendment set forth below was given in a telephone interview with Fei-Fei Chao, Ph.D. on August 28, 2006.

Claims 8 and 10 are canceled.

In claim 5, line 3, "optionally" is deleted and on line 4, following "a first-pass effect", -- selected from the group consisting of erythromycin, felodipine, troleandomycin, nifedipine, cyclosporine, FK506, terfenadine, tamoxifen, lidocaine, triazolam, dapson, diltiazem, lovastatin, simvastatin, quinidine, ethyl estradiol, testosterone, midazolam and alfentanil -- is inserted.

In claims 9 and 11, line 1, "8" is deleted and -- 5 -- is inserted therefor.

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The following is an Examiner's statement of Reasons for Allowance:

The drawings included in the present disclosure, as well as the Examples on pages 1-22, show, respectively, an increase in the absorption and bioavailability of simvastatin when administered with the CYP3A inhibitor catechin in an animal model and, in Table 1, pages 16-18, the demonstrated inhibition of CYP3A activity following administration of various compounds. To one skilled in the art, in view of the demonstrated efficacy of swertiamarin to inhibit CYP3A activity, it would have been reasonable to expect swertiamarin to exhibit the same property of increasing absorption and bioavailability of drugs that undergo a first pass effect.

Yamahara et al., Yakugaku Zasshi (1978), 98(11), 1446-51 (abstract), Lei et al., Zhongcaoyao (1982), 13(8), 369-9 (abstract) and Hikino et al., Shoyakugaku Zasshi (1984), 38(4), 359-60 (abstract), are cited to show further the state of the art with respect to pharmaceutical compositions comprising swertiamarin.

Any comments considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

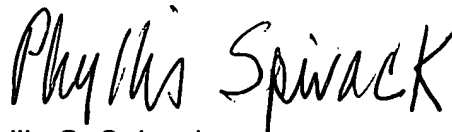
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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 6, 2006



Phyllis G. Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**